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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| LEITH, PATRICIA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/772,099 | HALEY, JEFFREY T. | |
| | Examiner | Art Unit | |
| | Patricia Leith | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1, 3-5, 10-15, 17-18, 23-28 and 45-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 10-15, 17-18, 23-28 and 45-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/31/04,12/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1, 3-5, 10-15, 17-18, 23-28 and 45-58 are pending in the application and were examined on their merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 10-15, 17-18, 23-28 and 45-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-5, 10-15, 17-18, 23-28 and 45-58 either recite, or depend upon a claim which recites 'extract of licorice root'. It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of extracts.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* extracts. The possible variations of extracts are limitless. Although Applicant has disclosed one extract of licorice root, this disclosure is actually a *very few* number in comparison to the enormous, *potentially millions* of types of extracts which could be obtained from licorice root'. The reason for this large amount of permutations is because extraction techniques are often coupled in order to obtain a product; for example

1) a water extraction followed by an alcoholic extraction: the product obtained is an extract.

2) a supercritical extraction ($CO_2$) followed by an alcoholic and then a non-polar solvent extraction (e.g., chloroform): the product is an extract.

3) a benzene extraction followed by a water extraction and chromatographic separation: the product is an extract.

4) a water/chloroform extraction (e.g., in a seperatory funnel), followed by collection of the water layer, chromatographic separation and crystallization of an isolate: the product is an extract.

5) squeezing the plant to obtain a juice: the product is an extract.

6) dipping the plant in an organic solvent to remove the waxy layer: the product is an extract.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F. 3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398. The specification lacks sufficient variety of species of extracts to reflect this variance in the

genus since the specification does not provide sufficient examples of such a genus of extracts.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of 'extract' and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention and thus, this rejection is proper.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 10-15, 17-18 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vedros (US 5,198,217) in view of Biegajski et al. (US 5,700,478).

Vedros (US 5,198,217) teach a method for treating inflammatory diseases of the skin, including ulcers in oral tissues by topical (oral) administration of a composition comprising licorice root extract containing glycyrrhizin as well as carriers such as carrageenan (see Abstract, col.2, lines 33-42, col. 3, lines 40-46 and col. 4, lines 52-61).

Vedros did not specifically teach wherein the pharmaceutical composition was in the form of an adhesive oral patch or wherein the composition was released the licorice extract for over more than 30 minutes or wherein the composition was in a package instructing recipients of the patches to hold the patches in their mouths on or near a canker sore at least two or more hours per day to treat mouth ulcers, wherein the gum was specifically a gum as recited in claims 11-14.

Transmucosal delivery of active agents to relive symptoms of mouth ulcers in the form of patches were known in the art at the time the invention was made. Biegajski et al. (US 5,700,478) for example, disclosed an adhesive oral patch for pharmaceutical delivery (see entire reference, particularly the Abstract and col.7). Biegajski et al. specifically disclosed the use of several types of gums which were suitable in the

making of such patches; for example, xanthan gum as well as karaya gum (col.8, lines 60-61).

One of ordinary skill in the art would have been motivated to have formulated the composition disclosed by '217 into a transmucosal patch in order to create a pharmaceutical product which released medicine over an extended period of time, thereby relieving pain and discomfort of the patient. It was clear from '217 that the composition comprising licorice root extract which was the active agent, provided relief from pain. The ordinary artisan would have had a reasonable expectation that if the composition were present in a transmucosal patch, the active agent would have been delivered to the patient over a longer period of time.

Although '217 does not specifically teach wherein the gum was specifically a gum as recited by claims 11-14, it is deemed that one of ordinary skill in the art would have been motivated to substitute the gums of claims 11-14 because these gums are functional equivalents to carrageenan in that they are all known to be fillers/carriers for pharmaceuticals.

Glycyrrhetenic acid is a derivative of glycyrrhizin. Thus, although '217 does not specifically teach that glycyrrhetenic acid is present in the licorice extract, it is deemed that the compound would have been intrinsic to the extract since the extraction

procedure would have necessarily extracted both compounds due to their similar polarities especially lacking convincing evidence to the contrary.

Claims 45-58 are free of the art.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

12/22/05